IN THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

CASE NO. _____

IMS HEALTH INCORPORATED; VERISPAN, LLC; and SOURCE HEALTHCARE ANALYTICS, INC., a subsidiary of WOLTERS KLUWER, HEALTH INC.,	
Plaintiffs,	PRELIMINARY & PERMANENT INJUNCTIVE RELIEF SOUGHT BEFORE JAN. 1, 2008
vs.	
WILLIAM H. SORRELL, as Attorney General of the State of Vermont,	
Defendant.	

2:07-cv-188

Complaint for Declaratory & Injunctive
Relief with Respect to Vt. Stat. Ann. tit. 18, § 4631 (2007)

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INTRODUCTION

Plaintiffs, IMS Health Incorporated, Verispan, LLC, and Source Healthcare Analytics, Inc. sue the defendant, William H. Sorrell, as Attorney General of the State of Vermont, and state:

1. This is an action to declare Vt. Acts No. 80, § 17 (2007), codified as Vt. Stat. Ann. tit. 18, § 4631 (2007) (hereinafter "the Prescription Restraint Law"[1] or "the law"), unconstitutional and to preliminarily and permanently enjoin its enforcement. The law violates the First and Fourteenth Amendments of the United States Constitution by prohibiting the communication of lawfully-obtained, truthful, important information without directly advancing important or substantial government interests when alternatives that do not restrict speech are available to achieve the state's objectives. The law also violates the Commerce Clause of the United States Constitution by regulating transactions that take place wholly outside of Vermont and is preempted by federal law.

2. Plaintiffs, the "health information publishers," are the world's leading providers of information, research, and analysis to the pharmaceutical and health care industries. Plaintiffs provide a vital link between physicians and pharmaceutical manufacturers, medical researchers, health economists and regulatory agencies – a link that helps improve public health and ensure patient safety through the collection, analysis, and reporting of vast amounts of information regarding the drugs that doctors prescribe. For more than a decade, this work has helped to ensure that the right doctors receive the right information about the right drugs so that the doctors can make the right choices for their patients. At the same time, this work always has

[1] This is not the official title of the law. The official title is "An Act Relating to Increasing Transparency of Prescription Drug Pricing and Information." Plaintiffs use the different title for brevity and to emphasize that the effect of the law is to restrain publication of prescription information, not to make drug pricing or information transparent.

safeguarded patient privacy.

3. Last year, the state of New Hampshire enacted an extraordinary law – the first of its kind in the United States – that attempted to put an end to this work by prohibiting pharmacies and similar entities from communicating lawfully-obtained, truthful information about doctors' prescribing practices in prescription records. The State of New Hampshire enacted the law on the basis of speculation that restricting targeted marketing by pharmaceutical companies by cutting off the flow of information about doctors' prescribing practices would lower healthcare costs in that state. The State also passed the law in order to keep physician prescription decisions from public scrutiny.

4. Two of the plaintiffs in this suit challenged the constitutionality of the New Hampshire law because the prohibition against communications concerning the prescription decisions of New Hampshire doctors violated the health information publishers' First Amendment Rights without directly advancing a substantial governmental interest and because the state had other alternative means to achieve its goals without infringing on plaintiffs' First Amendment rights.

5. At the same time that the New Hampshire district court was considering the New Hampshire law, the Vermont Legislature took steps to enact similar legislation. Section 17 of Vermont Senate Bill No. 115 (2007), as originally proposed, was modeled after and was almost identical to the New Hampshire Prescription Information Law.

6. Before the Vermont law was enacted, however, the New Hampshire district court declared the New Hampshire law unconstitutional and permanently enjoined its enforcement. *See IMS Health Inc. v. Ayotte,* 490 F. Supp. 2d 163 (D.N.H. April 30, 2007), *appeal docketed,* No. 07-1945 (1st Cir. June 20, 2007).

7. The Vermont Legislature then hastily amended its bill to try to avoid constitutional defects found in the New Hampshire legislation. In doing so, it made the legislation even more constitutionally suspect by vesting in prescribers themselves the decision as to whether the speech of third parties will be restrained. This increases the danger that the law will be used to shield poor prescribing practices and that this will increase, rather than decrease, the rising costs of healthcare. In addition, legislative findings were hastily added to the Vermont bill only after the New Hampshire court ruled that a legislative body is not entitled to deference when it does not make findings. The so-called "findings" are little more than conclusory statements based on no actual evidence of any connection between the supposed ill the law is intended to cure – rising drug costs – and the publication of truthful prescribing information conveyed by entities such as the plaintiffs.

8. Nevertheless, on June 9, 2007, the Vermont governor signed the bill into law, and it became 2007 Vt. Acts No. 80, which becomes effective on January 1, 2008.[2] Section 17 of Vermont Act No. 80, codified as Vt. Stat. Ann. tit. 18, § 4631 (2007), contains the provisions attacked in this complaint as unconstitutional. Section 1 of Vermont Act No. 80 contains findings that purportedly justify the law. By restraining publication of vital prescribing information, Vermont's new law, much like the New Hampshire law, will violate plaintiffs' First Amendment rights without directly advancing any substantial governmental interest.

9. The American Medical Association, which opposes restrictions on the collection and disclosure of physician prescribing data, has observed that prescriber level data "is critical to improving the quality, safety and efficacy of pharmaceutical prescribing through evidence-based medical research." Just as critical, the Vermont law is contrary to the national movement toward

[2] A copy of 2007 Vt. Acts No. 80, as enacted into law, is attached hereto as Exhibit A.

more transparency in healthcare practices. The success of initiatives designed to improve healthcare quality, ensure patient safety and manage costs depends on publication of more information – not less. Without prescriber-identifiable data, the healthcare community will lose a powerful tool to help monitor the safety of new medications and ensure that patients taking them are not harmed. Without such information, medical researchers will be unable to conduct studies that can improve public health. Without it, pharmaceutical and biotechnology companies will be deprived of information necessary to effectively comply with federal safety regulations, implement drug recall programs and communicate to prescribers information about innovative, life-saving treatments. In sum, by restraining publication of prescriber-identifiable data, the Vermont law takes healthcare in the wrong direction while doing nothing to improve the well-being of Vermont's citizens.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337 and 1343(a)(3) and (4), because the action arises under the Commerce Clause, the Supremacy Clause and the First and Fourteenth Amendments to the United States Constitution and under 21 U.S.C. §§ 301 et seq. and 42 U.S.C. §§ 1983 & 1988.

11. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c), because plaintiffs' claims arise in this district and the defendant is a public official located within this district.

THE PARTIES

12. Plaintiff, IMS Health Incorporated ("IMS Health"), is a Delaware corporation with its principal place of business for U.S. operations in Plymouth Meeting, Pennsylvania.

13. Plaintiff, Verispan, LLC, ("Verispan"), is a Delaware limited liability company with its principal place of business in Yardley, Pennsylvania.

14. Plaintiff, Source Healthcare Analytics, Inc. ("Source Healthcare"), is a Delaware corporation and a wholly owned subsidiary of Wolters Kluwer Health, Inc., with its principal place of business in Phoenix, Arizona.

15. Defendant, William H. Sorrell, is the Attorney General of the State of Vermont and the chief legal officer charged with the responsibility of enforcing Vt. Stat. Ann. tit. 18, § 4631 (2007).

OTHER COMMON FACTUAL ALLEGATIONS

The following allegations are common to all of the counts of the complaint:

Publishing Activities of IMS Health Incorporated

16. IMS Health is a publicly traded company that was founded as Intercontinental Marketing Services in 1954. IMS Health is the world's leading provider of information, research and analysis to the pharmaceutical and healthcare industries, with data collection and reporting activities in over 100 countries. The company receives and processes vast quantities of health care data each year. In the United States alone, IMS Health collects information from thousands of sources: pharmaceutical wholesalers, pharmacies, physicians, hospitals, and clinics, and processes millions of records each week. The information collected is then aggregated with other information, analyzed and made available to IMS Health's subscribers through dozens of services designed to help them drive decisions and shape strategies. All of IMS Health's proprietary databases are composed of patient de-identified data. This means that IMS Health neither uses nor transfers information that contains the identity of patients in any of its subscription services.

17. IMS Health's subscribers include pharmaceutical companies, biotechnology firms, pharmaceutical distributors, government agencies, consulting organizations, the financial community and others. In addition, IMS Health frequently makes information available without charge to academic researchers (researchers at universities throughout the United States), medical researchers (researchers at the Centers for Disease Control, the Institutes of Medicine of the National Academy of Science, the Mayo Clinic and Memorial Sloan-Kettering), humanitarian organizations (American Red Cross), law enforcement authorities (state attorney generals, U.S. Department of Justice, the U.S. Federal Trade Commission, and the U.S. Drug Enforcement Administration), and industry observers (journalists). With the aid of IMS Health's vast amount of data, these individuals and organizations are able to track patterns of disease and treatment, conduct outcomes research, implement best practices, and apply health economic analyses. The company's databases are essential to effective implementation of prescription drug recall programs, performance of pharmaceutical market studies, efficient pharmaceutical sales and marketing resource allocation, and assessment of drug utilization patterns (*e.g.*, on-and-off label uses and regional variations in physician prescribing behavior).

18. IMS Health's prescriber-level databases are also essential to support research, analysis, development and implementation of practice guidelines and public health policy for the advancement of patient health. Examples of these activities include:

a. Asthma in low income areas. A study in New York used IMS Health's prescriber-level information to examine physician-prescribing patterns in under-served urban areas to determine patterns of under-treatment of patients with asthma. There was substantial evidence that asthma controller medications were underutilized, which reflected issues in both physician education and public perceptions. Feedback on the study findings was provided to

physicians to engage them in implementing appropriate public health solutions.

b. Community intervention to reduce overuse of antibiotics. A research study relied on IMS Health's prescriber-level data to complete a pediatric study on the judicious use of antibiotics. The objective of the study was to assess the impact of parent and clinician education on antibiotic prescribing and carriage of penicillin-nonsusceptible streptococcus pneumonia in children. The study resulted in a multifaceted education program that led to community-wide reductions in antibiotic prescribing.

c. Regional impact of bioterrorist threats on prescribing. Wisconsin researchers at the Marshfield Clinic Research Foundation used IMS Health's prescriber-level information to determine if the public demand for fluoroquinolones, such as Cipro, post-9/11 bioterrorist threats would spread to communities not directly affected by anthrax scares in New York, New Jersey, Connecticut, Pennsylvania, Virginia, Maryland and Florida.

Publishing Activities of Verispan LLC

19. Verispan is a healthcare information publisher founded by Quintiles Transnational Corp. and McKesson Corp. Verispan is one of the major providers of healthcare information in the United States. Since its founding as Scott-Levin Associates, Inc. in 1982 and along with its constituent companies formerly known as Kelly-Waldron, SMG, Synergy, and Amaxis, Verispan has served the pharmaceutical and healthcare industries in the United States with an important source of healthcare information. Verispan contracts to receive nearly half of all U.S. prescriptions and nearly one-quarter of all U.S. electronic medical transactions annually. Verispan captures a sample of data from a near-census of U.S. retail pharmacies. By focusing on breadth of data coverage, Verispan is able to improve insight into prescription and medical activity at the national, regional and individual prescriber level.

20. All of Verispan's proprietary databases are composed of patient de-identified data. This means that Verispan neither uses nor transfers information that contains the identity of patients in any of its subscription services. With the aid of Verispan's vast amount of data, the medical, scientific, pharmaceutical and healthcare management communities are able to track patterns of disease and treatment, conduct outcomes research, implement best practices, and apply health economic analyses. The company's databases, including physician-identifiable data, are essential to effective implementation of prescription drug recall programs, performance of pharmaceutical market studies, efficient pharmaceutical sales and marketing resource allocation, and assessment of drug utilization patterns (*e.g.*, on-and-off label uses and regional variations in physician prescribing behavior).

21. Verispan's databases are also essential to the effective implementation of healthcare studies. For example, Verispan's data is currently used by the Department of Health and Human Services through the Food and Drug Administration. The FDA uses Verispan de-identified prescription data to monitor the incidence by which any two dispensed drugs are used with one another. This is used by FDA as the backing to many interaction studies they perform in assessing the safety of ethical prescription medications. Verispan's data has also been used by many of its subscribers to effectively identify eligible prescribers for clinical trials. In these cases accurate prescriber level data is crucial to perform accurate and expeditious clinical trials, which may provide critical healthcare options to patients in need of alternative treatment.

Publishing Activities of Source Healthcare Analytics, Inc.

22. Wolters Kluwer is a leading multinational publisher and information services company active in many markets. One division, Wolters Kluwer Health, Inc. ("Wolters Kluwer Health"), a wholly owned subsidiary of Wolters Kluwer U.S. Corporation, is a primary supplier

of information to professionals and students in the fields of medicine, nursing, allied health, and pharmacy, as well as entities in the pharmaceutical industry. It produces textbooks, reference products, journals, and other informational materials that professionals employ in the knowledge-intensive, rapidly changing practice of medicine. Source Healthcare Analytics, Inc. ("Source Healthcare"), a wholly owned subsidiary of Wolters Kluwer Health, sells a variety of information products that use "prescriber-identified prescription data," i.e., records that match prescriptions to prescribers. To create these information products, Source Healthcare purchases prescriber-identified data from pharmacies or other originating entities, then aggregates, analyzes, and packages it for use by subscribers and other customers.

23. Source Healthcare's subscribers and other customers use the data in a broad range of activities. For example, pharmaceutical manufacturers use it to identify doctors who may be interested in their products and who may have patients who would be suitable participants in clinical trials of promising new drugs. Source Healthcare's subscribers and customers use the data to report to governmental agencies, including the FDA, discharging their regulatory and law enforcement responsibilities. Products like Source Healthcare's can help governmental agencies direct drug safety alert letters toward doctors whose prescribing practices make them relevant, and enforce civil and criminal laws against abusive prescribing practices. In addition, a variety of individuals and organizations use the data in research concerning drug usage, interactions, effectiveness, and costs.

The Information at Issue: Prescriber-Identifiable Data

24. In the United States, approximately 1.4 million prescribers are licensed to write prescriptions. Prescriptions are written for approximately 8,000 different pharmaceutical products, and many of these products are dispensed in various forms, strengths, and doses.

25. Prescriptions are dispensed by approximately 54,000 retail pharmacies throughout the United States, as well as other medical facilities licensed to fill prescriptions.

26. Retail pharmacies in the United States are primarily composed of chain pharmacies, independent pharmacies, mass merchandisers and food stores with in-store pharmacies, mail order pharmacies, and long-term care pharmacies.

27. Retail pharmacies acquire prescription data during the regular course of business. For each prescription filled, a record is kept that includes the name of the patient, information identifying the prescriber, the name, dosage and quantity of the prescribed drug, and the date the prescription is filled. If the pharmacy is part of a larger organization with multiple retail outlets, each outlet's prescription data is ultimately aggregated with data from other outlets and stored in a central location.

28. After retail pharmacies acquire prescription data, they then license, sell, or transfer the data (without disclosing the patient's identity) to health information publishers for two distinct purposes. First, in order to make a profit. Second, they license, sell, or transfer the information to the health information publishers because those companies have developed sophisticated methods of aggregating and analyzing the information in order to make the information useful to entities that devote substantial resources to improving the health and welfare of consumers.

29. The patient de-identified information that the health information publishers purchase from pharmacies and similar entities include: the name of the pharmaceutical product, information identifying the prescriber, the name, dosage and quantity of the prescribed drug, and the date the prescription is filled.

30. Currently, health information publishers collectively acquire, aggregate and analyze information relating to billions of prescription transactions per year throughout the United States.

31. Plaintiffs acquire, license, sell, use, or transfer the information for two distinct purposes. First, to make a profit. Second, to improve public health and welfare by licensing, selling, and transferring it to pharmaceutical companies and to other entities that devote substantial resources to using the information to improve the health and welfare of consumers.

32. Some of the entities to which the plaintiffs license, sell, or transfer the information use the information for advertising, marketing, and promotional purposes. These entities and others also use the information for other purposes that are not associated in any way with advertising, marketing, and promotional purposes.

33. Plaintiffs strongly believe that the widespread dissemination and use of the prescription information that they gather and analyze improves the health and welfare of consumers.

How the Prescription Information Is Gathered & Published

34. Plaintiffs purchase prescriber-identifiable data from participating pharmacies and other sources. To comply with state and federal laws regarding patient privacy, participating pharmacies allow plaintiffs to install software on their computers that encrypts any information identifying the patients before it its transferred to plaintiffs' computers. After patient information is de-identified in this way, a number is assigned to each de-identified patient that permits prescription information to be correlated for each patient but does not allow the patient's identity to be determined. The prescription information is then transferred to the plaintiffs' computers.

35. Plaintiffs obtain all of their prescription information, including information on prescriptions filled in Vermont, from computers that are located outside of Vermont.

36. Plaintiffs add value to prescriber-identifiable data by combining the data with prescriber reference information contained in their databases. This allows the plaintiffs to, among other things (a) match each prescription to the correct prescriber, (b) identify and use the correct name of the prescriber, and (c) add address, specialty and other professional information about the prescriber to the prescription data. Prescriber reference files are created using information obtained from various sources, including the American Medical Association's Physician Masterfile. The AMA's Masterfile contains demographic, educational, certification, licensure, and specialty information for more than 800,000 active U.S. medical doctors (MDs) and over 90% of the doctors of osteopathy (DOs), including members and nonmembers alike.[3] The health information publishers use the patient de-identified prescription data, together with the reference file information, to produce a variety of databases.

37. Plaintiffs use these databases to create a number of different reports and services regarding prescribed pharmaceutical products, some of which include prescriber-identifiable information and some of which is aggregated and reported at a broader geographic level. Plaintiffs then license the information from these reports and services to third parties for many different uses.

38. The patient de-identified prescription data that the plaintiffs supply to their pharmaceutical and biotechnology subscribers are used for many purposes. The prescription data, for example, are used by these subscribers to:

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[3] As of July 1, 2006, the AMA has made it possible for all physicians, including those in Vermont, to choose whether to prevent the release of prescriber-identifiable information about them to pharmaceutical sales representatives by participating in the Prescribing Data Restriction Program ("PDRP"). *See* www.ama-assn.org/go/prescribingdata.

a. Prioritize the release of public safety news alerts based on physician prescribing details;

b. Accelerate innovation through insight into the needs and habits of those whose health the new drugs are designed to improve;

c. Determine which products to develop and license and which acquisitions to consider;

d. Disseminate effectively and quickly vital, life-prolonging information to those prescribers for whom the information is relevant and most useful;

e. Allocate effectively valuable, life-prolonging sample medications to those prescribers whose patients need them most and are more likely to use them;

f. Determine whether a particular prescriber is prescribing products that the pharmaceutical companies have determined to be inappropriate in light of the development of new products that may be more effective, safer, or less expensive;

g. Implement prescription drug recall programs;

h. Evaluate, segment, target, size, compensate and deploy its sales force;

i. Allocate limited marketing resources to individual prescribers in a manner that reduces cost and saves time; and

j. Understand managed care's effect on the U.S. pharmaceutical marketplace.

39. Plaintiffs also provide patient de-identified prescription data without charge to academic researchers, medical researchers, government agencies, industry observers and others for a variety of purposes that are unrelated to the sale of a particular product.

40. Plaintiffs do not sell, market or promote pharmaceutical products or drugs to prescribers.

41. Patient de-identified prescription information without prescriber-identifiable information is not an adequate substitute for accurate information regarding the actual prescriptions written by individual physicians for many reasons, including: (a) pharmacies fill prescriptions that come from distant prescribers, (b) information from pharmacies frequently

does not include accurate zip code information for the prescriber, (c) information from pharmacies does not include the specialty of the prescribers who wrote the prescription, (d) the information is not useful for all of the uses described in paragraphs 38-39 above, and (e) significant errors in the information cannot be ascertained.

History of the Prescription Restraint Law

42. The sponsors of the Prescription Restraint Law have asserted that restrictions on the use or disclosure of prescriber-identifiable prescribing information are necessary for two reasons: to protect the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs. They have argued that the disclosure of prescriber-identifiable information to pharmaceutical companies gives pharmaceutical sales representatives (also known as "detailers") too much insight into prescriber behavior that often leads to inappropriate confrontation or coercion of prescribers about the products they prescribe.

43. The sponsors and supporters of the Prescription Restraint Law have also argued that (a) pharmaceutical sales representatives usually sell new branded drugs, (b) branded drugs are more expensive than generic drugs, and (c) by knowing the behavior of prescribers, the sales representatives will be better equipped to target their advertising and persuade the doctors to prescribe the branded drugs over the less costly generic drugs.

44. These assertions ignore that pharmaceutical sales have occurred for decades and the Prescription Restraint Law does nothing to stop or regulate inappropriate detailing practices. More importantly, the assertions made to justify the enactment of the Prescription Restraint Law make the following unstated assumptions: (a) prescribers, all of whom are highly-educated and licensed healthcare professionals, are incapable of evaluating for themselves truthful and

accurate information regarding their own prescribing practices, rejecting or simply ignoring such information if they do not find it significant; (b) prescribers are unable to consider information from various sources (including information from pharmaceutical companies) to make a professional judgment regarding the most appropriate medication for each patient; (c) higher cost branded pharmaceuticals will always result in higher overall costs of patient care; and (d) if government regulators decide what information should be communicated by pharmaceutical companies, then the cost of prescription drugs to consumers will decline. These assumptions are unsupported by experience, evidence, or logic.

45. No studies have been performed that would support the conclusion that the price of prescription drugs would decrease if pharmaceutical companies were unable to use prescriber information in connection with their targeted marketing activities. In fact, the price of prescription drugs may increase because the costs associated with marketing pharmaceutical drugs are likely to increase as pharmaceutical companies are unable to focus their resources to the relevant market. In addition, overall healthcare costs are likely to increase because prescribers will have less information regarding the drugs they should be prescribing.

46. The legislative history of the Prescription Restraint Law reflects that the Vermont Legislature had intended to enact a law that would have been similar to the New Hampshire law, but that when the Legislature learned that the New Hampshire law had been declared unconstitutional, it created findings to attempt to support the bill within a matter of several days and amended the bill to allow the use of prescriber-identifiable data in prescription records for marketing or promoting a prescription drug if (a) the prescriber who is the subject of the information expressly consents to such use, and (b) the entity using the information for such purpose makes certain disclosures to be provided for by rule.

The Prescription Restraint Law

47. The Prescription Restraint Law, as enacted, Vt. Acts No. 80 § 17 (2007), amended title 18 of the Vermont Statutes to provide:

§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

(a) It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

(b) As used in this section:

(1) "Electronic transmission intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices used by health care professionals, prescribers, pharmacies, health care facilities and pharmacy benefit managers, health insurers, third-party administrators, and agents and contractors of those persons in order to facilitate the secure transmission of an individual's prescription drug order, refill, authorization request, claim, payment, or other prescription drug information.

(2) "Health care facility" shall have the same meaning as in section 9402 of this title.

(3) "Health care professional" shall have the same meaning as in section 9402 of this title.

(4) "Health insurer" shall have the same meaning as in section 9410 of this title.

(5) "Marketing" shall include advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

(6) "Pharmacy" means any individual or entity licensed or registered under chapter 36 of Title 26.

(7) "Prescriber" means an individual allowed by law to prescribe and administer prescription drugs in the course of professional practice.

(8) "Promotion" or "promote" means any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance.

(9) "Regulated records" means information or documentation from a prescription written by a prescriber doing business in Vermont or a prescription dispensed in Vermont.

(c)(1) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data-sharing program to allow a prescriber to give consent for his or her identifying information to be used for the purposes described under subsection (d) of this section. The department and office shall solicit the prescriber's consent on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her consent. The department and office may establish rules for this program.

(2) The department or office shall make available the list of prescribers who have consented to sharing their information. Entities who wish to use the information as provided for in this section shall review the list at minimum every six months.

(d) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity may use regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug only if:

(1)(A) a prescriber has provided consent for the use of that data as provided in subsection (c) of this section; and

(B) the entity using the regulated records complies with the disclosure requirements in subsection (f) of this section; or

(2) the entity meets one of the exceptions provided in subsection (e) of this section.

(e) This section shall not apply to:

(1) the license, transfer, use, or sale of regulated records for the limited purposes of pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a health care professional, the patient's health insurer, or the agent of either; or health care research;

(2) the dispensing of prescription medications to a patient or to the patient's authorized representative;

(3) the transmission of prescription information between an authorized prescriber and a licensed pharmacy, between licensed pharmacies, or that may occur in the event a pharmacy's ownership is changed or transferred;

(4) care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy and other information relating to the drug being dispensed, treatment options, recall or patient safety notices, or clinical trials;

(5) the collection, use, or disclosure of prescription information or other regulatory activity as authorized by chapter 84, chapter 84A, or section 9410 of this title, or as otherwise provided by law;

(6) the collection and transmission of prescription information to a Vermont or federal law enforcement officer engaged in his or her official duties as otherwise provided by law; and

(7) the collection, use, transfer, or sale of patient and prescriber data for marketing or promoting if the data do not identify a prescriber, and there is no reasonable basis to believe that the data provided could be used to identify a prescriber.

(f) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs as provided for under this section, the marketer shall disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options. As necessary, the office of Vermont health access, in consultation with the department of health, the area centers on health education, the office of professional regulation, and the office of the attorney general, shall develop rules for compliance with this subsection, including the certification of materials which are evidence-based as defined in section 4621 of this title and which conditions have evidence-based treatment guidelines. The rules shall be consistent with the federal Food and Drug Administration's regulations regarding false and misleading advertising. To the extent practicable, the rules shall use the evidence-based standards developed by the blueprint for health.

(g) In addition to any other remedy provided by law, the attorney general may file an action in superior court for a violation of this section or of any rules adopted under this section by the attorney general. The attorney general shall

> have the same authority to investigate and to obtain remedies as if the action were brought under the Vermont consumer fraud act, chapter 63 of Title 9. Each violation of this section or of any rules adopted under this section by the attorney general constitutes a separate civil violation for which the attorney general may obtain relief.

Violations of the Law are Punishable by Severe Penalties

48. Section 21 of Vt. Acts No. 80 (2007) amends 9 V.S.A., chapter 63, to make a violation of section 17 a violation of the consumer protection and false advertising laws. Chapter 63 authorizes injunctive relief and the imposition of a civil penalty of not more than $10,000.00 for each violation of its general provisions); imprisonment of up to 18 months or fines not more than $10,000, or both, for making prohibited telephone solicitations; and imprisonment of up to 1 year or fines not more than $1,000, or both, for violations of children's product safety provisions. The new law leaves unclear whether all of these civil and criminal remedies are available to punish a violation of the Prescription Restraint Law. Because the plaintiffs acquire and publish millions of discrete pieces of information from regulated records, the Attorney General could seek to impose vast penalties on the plaintiffs and their sources, subscribers, or customers if they continued to engage in their ordinary business practices after the effective date of the law.

Damage Inflicted by the Law on the Plaintiffs & Others

49. The Prescription Restraint Law imposes serious and irreparable injury on (a) the plaintiffs' use of regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug, (b) pharmacies' and other entities' use of regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug, and (c) pharmaceutical companies, health care researchers, prescribers, and patients, all of whom benefit from the plaintiffs' and other entities' use of regulated records which include prescription

information containing prescriber-identifiable data for marketing or promoting a prescription drug.

50. If the health information publishers cannot use the information other than for purposes identified as permissible in the Prescription Restraint Law, neither the health information publishers nor any other persons or entities will be able to continue acquiring the information, aggregating the information, analyzing the information, and distributing the information to third parties, either for purposes allowed or for purposes prohibited by the Prescription Restraint Law.

51. It is highly improbable that a significant number of prescribers will avail themselves of the procedures to consent to the use of the regulated records for marketing and promotion of prescription drugs or that manufacturers that use the information from the regulated records would or could agree to make disclosures required by the law in connection with their marketing and promotion activities. The law therefore will operate to freeze all or virtually all communication of prescriber identifiable information from the regulated records.

52. Section 24b of Vt. Acts No. 80 (2007) provides that the act shall become effective no later than January 1, 2008, except that the Department of Health and the Office of Professional Regulation may begin any necessary rulemaking, revision of forms, or other administrative actions necessary to implement the program, immediately upon passage. It also provides that the Department and Office may implement the Prescription Restraint Law for prescribers with licenses at the time of passage of the law when the prescriber next requests a renewal of the license.

The Imminent Threat & Reasonable Fear of Enforcement

53. After the law was enacted, plaintiffs' counsel wrote to the Attorney General's

office to determine whether the plaintiffs, their sources, and their subscribers would be subject to an enforcement action if they continued their existing business practices.

54. To date, the attorney general has provided no assurances that the law would not be enforced as soon as it becomes effective.

55. Plaintiffs have concrete plans to engage, after January 1, 2008, in activity proscribed by the law: purchasing and selling prescription information showing the prescribing practices of prescribers doing business in Vermont or whose prescriptions are filled in Vermont.

56. Plaintiffs have a reasonable fear that an action for injunctive relief and damages would be brought by the Attorney General if they execute those concrete plans on or after January 1, 2008.

Count I

The Prescription Restraint Law Violates the First Amendment by Prohibiting the Plaintiffs' Commercial Speech

57. Plaintiffs re-allege paragraphs 1 through 56 and incorporate them herein by reference.

58. The Prescription Restraint Law prohibits commercial speech through its restriction on the use of records relative to prescription information containing prescriber-identifiable data for specified "marketing" and "promotional" purposes.

59. The Prescription Restraint Law does not directly advance the interests that it purports to serve. Indeed, the statute appears to be taking the most indirect route that it possibly could take to achieve its objectives. Instead of imposing direct regulations on the manner in which pharmaceutical companies market their products or the pricing of the products, the statute attempts to prevent the information that pharmaceutical companies would like to consider in deciding how to market their products from being licensed, sold, used or transferred for any of a

broad range of commercial purposes, many of which may be unrelated to advertising. The State of Vermont may regulate the marketing or promotional practices or the pricing decisions of pharmaceutical companies, but it may not, without violating the First Amendment, do so indirectly by imposing restrictions on the dissemination of truthful information used by such companies to make advertising and other decisions in the hope that such indirect regulation will have the intended regulatory effect. There is no evidence, of course, that the Prescription Restraint Law would directly advance any of the justifications that the State may assert justify the legislation. Imposition of direct regulation on the advertising and pricing of pharmaceutical companies itself raises a host of constitutional concerns, but the State should not be permitted to achieve indirectly by suppression of constitutionally protected speech what it is prohibited from regulating directly.

60. The Prescription Restraint Law also is broader than necessary to accomplish the interests that it purports to serve. The State of Vermont has either failed to implement and test or has rejected less restrictive alternatives to the Prescription Restraint Law. If it is the State's contention that prescribers are mis-prescribing pharmaceutical products for personal gain, the State can, among other things, prosecute physicians for engaging in such practices. If it is the State's contention that prescribers are being misled by pharmaceutical companies with false and misleading information, the State can, among other things, impose severe penalties on pharmaceutical companies for doing so. If it is the State's contention that prescribers do not have sufficient information concerning competing generic drugs that are not marketed by pharmaceutical companies, then the State can, among other things, provide additional information to prescribers or require education of prescribers in this regard as a condition of

continued licensing. None of these alternatives would require the suppression of constitutionally protected speech in order to achieve the State's objectives.

61. The Prescription Restraint Law therefore violates the First and Fourteenth Amendments of the United States Constitution as it is applied to the commercial speech in which the plaintiffs engage in the regular course of their business.

Count II

The Prescription Restraint Law Violates the First Amendment by Restricting the Plaintiffs' Non-Commercial Speech

62. Plaintiffs reallege paragraphs 1 through 56 and incorporate them herein by reference.

63. The Prescription Restraint Law prohibits the use of records relative to prescription information containing prescriber-identifiable data for specified "marketing" and "promotion" of prescription drugs.

64. "Marketing" is broadly defined in the statute as "advertising, promotion or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior or an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing force."

65. "Promotion" or "promote" is broadly defined in the statute as "any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance."

66. These definitions sweep within their ambit substantial non-commercial speech in which the plaintiffs engage that would not be regarded as "commercial speech."

67. The fact that information may be sold for a profit does not transform the speech into "marketing" or "promotion." Newspapers, magazines, and other publishers of information all sell information for a profit; yet their speech is recognized as "non-commercial" because it serves important public purposes unrelated to advertisement. Commercial speech is speech that does no more than propose a commercial transaction.

68. When pharmacies and other entities with prescription information sell patient de-identified information to the health information publishers, they are not proposing a commercial transaction, and certainly they are not engaged in marketing or promotion of a prescription drug. They are conveying truthful information that lawfully is in their possession to a third party that is interested in learning the information and using the information for a myriad of purposes, including both commercial purposes and non-commercial purposes. A substantial amount of the commercial purposes for which the information is obtained are for profit, but are not for the purpose of proposing a commercial transaction.

69. Many of the purposes for which the information is obtained are not for advertising, promotional, or marketing activities, but for purposes that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual healthcare professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

70. When the plaintiffs license, sell or transfer patient de-identified prescription information to third parties, the third parties use the information for a myriad of purposes. While some of the uses to which they put the information are for the purpose of proposing a commercial transaction, many of the purposes to which they put the information are not for proposing a commercial transaction.

71. The Prescription Restraint Law restricts non-commercial speech on the basis of its content.

72. The State of Vermont lacks a compelling justification for prohibiting non-commercial speech through its prohibition against the use of prescription records containing prescriber-identifiable data by health insurers, self-insured employers, electronic transmission intermediaries, pharmacies or similar entities for "marketing" or "promotion" of prescription drugs, as those terms are broadly defined in the statute.

73. The Prescription Restraint Law is not the least restrictive means of achieving the purpose of the Prescription Restraint Law.

74. In addition, the Prescription Restraint Law is not limited in its operation to the imposition of fines upon violators; it also sets up a system of prior restraint against future speech that communicates truthful, important and lawfully-obtained information about a prescriber. Any system of prior restraint comes to this Court bearing a heavy presumption against its constitutional validity. In order to be constitutional, the statute must fit within one of the narrowly defined exceptions to the prohibition against prior restraints and must include procedural safeguards that reduce the danger of suppressing constitutionally protected speech. The statute does not fit within any recognized category of valid prior restraints, and it does not contain procedural safeguards that are required for a valid system of prior restraints.

75. The Prescription Restraint Law also lacks the procedural safeguards that are required to uphold a law that creates a system of prior restraint. The law prohibits private parties in *advance* of publication of publishing lawfully-obtained, truthful, and important information about the prescribing practices of individual prescribers. By allowing prescribers to lift the ban, the state has designated each prescriber as the licensor of the pharmacy's right to distribute

prescriber-identifiable data, but has defined no criteria to prevent exercise of this unfettered power for improper censorial purposes and no time restraints on when a prescriber would be required to act on a request to publish data pertaining to him or her. Accordingly, the law is an invalid restraint on speech.

76. The Prescription Restraint Law therefore violates the First and Fourteenth Amendments of the United States Constitution facially and as it is applied to the non-commercial speech in which the plaintiff health information publishers engage in the regular course of their businesses.

Count III

The Prescription Restraint Law is Void for Vagueness & Overbreadth

77. Plaintiffs reallege paragraphs 1 through 56 and incorporate them herein by reference.

78. The Prescription Restraint Law is vague and overbroad.

79. Section 4631(d), 18 Vt. Stat. Ann., provides that the covered entities may use regulated records which include prescription information containing prescriber identifiable data for marketing or promoting a prescription drug only if a prescriber has provided consent for the use of that data and the entity using the regulated records complies with certain disclosure requirements or the entity meets one of several specified exceptions.

80. Section 4631(b) defines "marketing" as "advertising, promotion or any activity that *is intended* to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior or an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing force." (emphasis added). This section makes it

unclear whether the use of covered data by a covered entity that merely is "intended to be used" for marketing or promotion, but is not actually used by the covered entity for such purposes, would violate the statute in the absence of consent and compliance with required disclosure requirements or the application of exceptions. Moreover, the definition does not specify whether the intended use refers to the intention of the pharmacy or similar entity, the intention of the health information publishers, or the intention of the pharmaceutical or biotechnology company that must be taken into account before prescriber-identifiable data can be used in a manner consistent with the statute. Further, the definition does not specify whether the controlling purpose or intent is the purpose at the time of the affected transaction or the purpose or intent at some subsequent time such as the time of the actual use of the information in marketing and promotion of prescription drugs.

81. Section 4631(d) does not state whether the marketing or promotion must be conducted by the acquirer of the information, the provider of the information, the ultimate consumer of the information, or some combination of all of these. The statute does not inform a reader which entity or person must conduct the marketing or promotion before running afoul of section 4631(d).

82. The disclosure requirements referenced in section 4631(d) are set forth in section 4631(f). It states:

> When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs as provided for under this section, the marketer shall disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options. As necessary, the office of Vermont health access, in consultation with the department of health, the area centers on health education, the office of professional regulation, and the office of

> the attorney general, shall develop rules for compliance with this subsection, including the certification of materials which are evidence-based as defined in section 4621 of this title and which conditions have evidence-based treatment guidelines. The rules shall be consistent with the federal Food and Drug Administration's regulations regarding false and misleading advertising. To the extent practicable, the rules shall use the evidence-based standards developed by the blueprint for health.

83. Section 4631(f) does not indicate what is meant by the language "as provided for under this section." It may mean that the disclosures must be made if the pharmaceutical marketer uses prescriber-identifiable data, or it may mean that disclosures must be made whether the pharmaceutical marketer uses prescriber-identifiable data or not.

84. Section 4631(f) fails to provide sufficiently specific criteria for the Office of Vermont Health Access (OVHA) to develop rules necessary to implement the disclosure requirements.

85. Section 4631(f) fails to impose any time limits on OVHA for developing rules necessary to implement the disclosure requirements.

86. OVHA cannot promulgate the rules required by section 4631(f) because thousands of drugs are being marketed and it is impossible to determine for each such drug the specific health benefits or risks of using *other* pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options.

87. Section 4631(f) fails to define what is meant by the term "other pharmaceutical drugs," and this term cannot reasonably be ascertained by either an ordinary reader or a highly sophisticated reader. The term not only is extraordinarily vague, but also constitutes an unlawful delegation of legislative authority.

88. Section 4631(f) requires the referenced rules to be "consistent with the federal Food and Drug Administration's regulations regarding false and misleading advertising."

OVHA cannot determine whether rules describing disclosure requirements for the thousands of drugs being marketed are "consistent" with such regulations.

89. The exceptions to the prohibition imposed by section 4631(d) include "patient care management," "utilization review," "health care research" or "as otherwise provided by law." The statute does not define these terms, and they are subject to broadly varying interpretations.

90. Section 4631(f) does not specify whether marketing that uses prescriber-identifiable data may continue without making the statutory disclosures until such time as OVHA promulgates rules that describe the disclosures that the statute requires; may continue until such time as OVHA promulgates rules that describe the disclosures that the statute requires, but must make the disclosures required by the statute itself; or must halt such marketing until such rules are promulgated. Thus, plaintiffs cannot determine from the vague language of the statute whether they may continue to sell prescriber-identifiable data for marketing purposes to pharmaceutical marketers even where they have the consent of prescribers to do so.

91. Even if OVHA were to adopt rules consistent with the requirements of section 4631(f) and pharmaceutical marketers were to assert that they would comply with the required disclosure requirements, the plaintiffs would have no means of reliably determining whether the pharmaceutical marketers were making the disclosures or whether such disclosures were in fact made in compliance with the statute and rules because the disclosures required by the statute are so vague. Nevertheless, the statute imposes severe penalties for communicating prescriber-identifiable data to pharmaceutical marketers for marketing purposes if the pharmaceutical marketers themselves fail to make the required disclosure. Under these circumstances, plaintiffs will not take the risk of communicating prescriber-identifiable data to pharmaceutical marketers

for marketing purposes even if rules are enacted describing the required disclosures and even if pharmaceutical marketers contend that they will comply with the rules and the statute and the plaintiffs have the consent of prescribers to use prescriber-identifiable data for marketing purposes.

92. Given the vague contours of the coverage and requirements of the statute, it will silence a substantial amount of speech that the state has no justification for silencing. Health information publishers, including the plaintiffs, no longer will communicate for *any* purpose information from prescription records that shows the prescribing practices of individual prescribers doing business in Vermont or whose prescriptions are dispensed in Vermont because of the real risk that they, their sources, and their subscribers and customers will be charged with violating the statute.

93. This law fails to give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he or she may act accordingly. It may trap the innocent by not providing fair warning.

94. The vagueness of the law also creates a risk of arbitrary and discriminatory enforcement by impermissibly delegating basic policy matters to administrative agencies, law enforcement officers, judges, and juries for resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application.

95. The vagueness of the Prescription Restraint Law also is a matter of special concern for two additional reasons:

a. First, the Prescription Restraint Law is a content based regulation of speech. The vagueness of such a regulation raises special First Amendment concerns because of its obvious chilling effect on free speech.

b. Second, the Prescription Restraint Law imposes severe monetary penalties and potential imprisonment for violations. The severity of the sanctions may well cause speakers to remain silent rather than communicate even arguably lawful words, ideas, and images. As a practical matter, this increased deterrent effect, coupled with the "risk of discriminatory enforcement" of vague regulations, poses grave First Amendment concerns.

96. The uncertain meaning of the law will force plaintiffs to "steer far wider of the unlawful zone than if the boundaries of the forbidden areas were clearly marked."

97. The Prescription Restraint Law accordingly violates the First and Fourteenth Amendments for vagueness and overbreadth.

Count IV

The Prescription Restraint Law Violates the Commerce Clause

98. Plaintiffs reallege paragraphs 1 through 56 and incorporate them herein by reference.

99. The Prescription Restraint Law impermissibly regulates conduct occurring wholly outside of Vermont.

100. The plaintiff health information publishers are located outside of Vermont. They collect outside of Vermont prescriber identifiable data relating to prescribers who do business in Vermont and whose prescriptions are dispensed in Vermont and store this data in databases located outside of Vermont. All of the prescriber identifiable data received by the health information publishers is supplied by companies located outside of Vermont. The Prescription

Restraint Law makes it illegal for pharmacies and other similar entities to continue providing prescriber identifiable data to the health information publishers for purposes restricted by the Prescription Restraint Law in the absence of prescriber consent and the making of certain disclosures or the applicability of various exceptions. As a result, all such data received by the health information publishers cannot be licensed, transferred, used, or sold anywhere, even outside of Vermont.

101. Accordingly, the Prescription Restraint Law violates the Commerce Clause of the United States Constitution.

Count V

The Prescription Restraint Law Is Preempted

102. Plaintiffs reallege paragraphs 1 through 56 and incorporate them herein by reference.

103. Congress has occupied the field of regulation of marketing of prescription drugs through enactment of the Federal Food, Drug and Cosmetic Act. 21 U.S.C. §§ 301 et seq.

104. Congress also has given the Food and Drug Administration (FDA) extensive authority to regulate communications between drug marketers and prescribers, and a pervasive scheme of federal regulation exists. The FDA has broad authority to regulate drug advertisements and promotional labeling.

105. The FDA itself has asserted that its authority preempts state law that imposes greater disclosure requirements on pharmaceutical manufacturers than those required by the FDA itself. See *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

106. The Prescription Restraint Law also requires pharmaceutical marketers who engage in marketing directly to a physician to make disclosures that are in conflict with federal law and the regulatory authority of the FDA.

107. Accordingly, the Prescription Restraint Law is preempted by the Food & Drug Act, the Food Drug & Cosmetic Act, regulations promulgated thereunder, and the FDA.

DEMAND FOR RELIEF

Wherefore the plaintiffs demand:

A. A declaration that the Prescription Restraint Law is unconstitutional, as applied to commercial speech.

B. A declaration that the Prescription Restraint Law is unconstitutional both facially and as applied to non-commercial speech.

C. A declaration that the Prescription Restraint Law is unconstitutional, both facially and as applied because it regulates speech using such vague and overly broad terms which will result in the silencing of an amount of protected speech that is proportionally vast when compared to the amount of unprotected speech, if any, that the law constitutionally may restrain.

D. A declaration that the Prescription Restraint Law violates the Commerce Clause of the United States Constitution by regulating transactions in commerce that take place wholly outside of the State of Vermont.

E. A declaration that the Prescription Restraint Law is preempted by the Federal Food Drug & Cosmetic Act, preambles, rules, and regulations thereunder, and by the FDA.

F. A permanent and preliminary injunction against the enforcement of the Prescription Restraint Law.

G. The costs and attorneys' fees that the plaintiffs have incurred in bringing this

action, as is provided for by 42 U.S.C. § 1988.

H. Such other relief that the Court may deem to be necessary or appropriate to afford the plaintiffs the full relief to which they are entitled.

Respectfully submitted,

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